[or '360'] tablets" and "Formula '90' Supplement Reducing * * * 15 Capsules * * * an additional aid to weight reducing – to be taken in conjunction with MpDs Super Protein Tablets * * * Each Tablet Contains: Sodium Carboxy Methyl Cellulose . . . . 8 grains Phenylasitin (conc. Prune) . . . 0.5 Mg."

ACCOMPANYING LABELING: Booklets entitled "Why Be Fat."

LIBELED: 3–5–58, Dist. Ariz.

CHARGE: 502(a)—the labeling of the *Super Protein Formula "90"* and the *Formula "90" Supplement*, when shipped, contain false and misleading representations that the articles contained no calories, would burn up extra fat, increase metabolism, and otherwise act as an adequate and effective treatment for obesity; and 502(f)(2)—the *Formula "90" Supplement* contained an irritant laxative, and its labeling failed to warn that it should not be used when symptoms of appendicitis were present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 5–7–58. Default—destruction.

5586. Trim-All capsules. (F.D.C. No. 41453. S. No. 23–306 P.)

QUANTITY: 3 drums containing a total of 41,500 capsules at North Hollywood, Calif.

SHIPPED: 11–6–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABELED IN PART: (Drum) "Lot No. 3218 * * * Special Formula #2 * * * Each capsule contains 60 mg. Phenylpropanolamine Hcl. 3 gr. Sodium Caseinate, 50 mg. Ascorbic Acid, 0.5 mg. Acetphenolisatin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of phenylpropanolamine Hcl and 64 percent of the labeled amount of ascorbic acid, of which the article released 90 percent of both in 2 hours. The article was intended to be repackaged and relabeled by the consignee as follows: "21 Trim-All Capsules (an Appetite Depressant) Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. Sodium Caseinate 3 gr. Dextrose 3 gr. Ascorbic acid 50 mg. Acetphenolisatin 0.5 mg. In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours.

LIBELED: 3–6–58, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess since it contained less than the labeled amounts of phenylpropanolamine Hcl and ascorbic acid, and it failed to release its ingredients over an 8-hour period; 502(a)—the label statements of the article, when shipped and while held for sale, namely, "Each capsule contains 60 mg. Phenylpropanolamine Hcl. * * * 50 mg. Ascorbic Acid" and "Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. * * * Ascorbic acid 50 mg. * * * In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours," were false and misleading; and 502(f)(2)—the article was a laxative, and its labeling, when shipped and while held for sale, failed to warn against use when symptoms of appendicitis are present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 3–26–58. Default—destruction.

5587. Salicon tablets. (F.D.C. No. 40953. S. No. 76–626 M.)

QUANTITY: 135 100-tablet btls., 61 30-tablet btls., and 60 12-tablet btls. at Portland, Maine.

SHIPPED: 9–30–57, from Boston, Mass., by K. A. Hughes Co.

LABEL IN PART: "Salicon * * * 5 Grain Tablets Active Ingredients: Acetylsalicylic acid (U.S.P. Aspirin) calcium carbonate and magnesium carbonate."

LIBELED: 11–14–57, Dist. Maine.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for nervous tension and sleeplessness; 502(f)(1)—the labeling of the article failed to bear adequate directions for use since, in lieu of a dosage statement for children under 3 years of age, its labeling failed to state that for the 3 year and under age group a physician should be consulted; and 502(f)(2)—its labeling failed to bear a warning against misuse by children since its labeling failed to warn that the product should be kept out of reach of children.

DISPOSITION: 1–7–58. Default—destruction.

5588. Zina-Ray oil, inhalers, and Ten Second Rub. (F.D.C. No. 41449. S. No. 24–906 P.)

QUANTITY: 1,080 1-oz. btls. and 284 3-oz. btls. of *Zina-Ray oil*, 26 cartons, each containing 1 gross of *inhalers*, and 1,065 1-oz. tubes and 265 3-oz. tubes of *Ten Second Rub* at Minneapolis, Minn., in possession of William R. Hall.

SHIPPED: Between 1–7–58 and 1–21–58, from Chicago, Ill.

LABEL IN PART: (Btl.) "Zina-Ray Oil * * * Contains eucalyptus oil, menthol, pine needle oil, peppermint oil"; (vial) "Inhaler Directions: Insert a few drops of * * * Zina-Ray Oil into the end of inhaler"; and (tube) "Ten Second Rub * * * Active ingredients: Lanolin, menthol, eucalyptus oil, peppermint oil, and pine needle oil."

LIBELED: 3–7–58, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Zina-Ray oil* and *inhalers*) for preventing headache, pain in the gums, neuralgia, deafness, arthritis, rheumatism, formation of crystal deposits in the bones, inflammation of the ear, pneumonia, "flu", and overcoming sinus infection and asthma, and (*Ten Second Rub*) for overcoming arthritis, rheumatism, and all aches and pains to which the body is subject, which were the purposes for which the articles were recommended orally by William R. Hall on 1–23–58.

DISPOSITION: 4–21–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5589. Chorionic gonadotropin. (F.D.C. No. 41363. S. No. 68–979 M.)

QUANTITY: 1,758 vials at New York, N.Y.

SHIPPED: 7–1–57, from Orange, N.J.

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than 2,500 International Units of chorionic gonadotropin potency per vial.

LIBELED: 1–21–58, S. Dist. N.Y.

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*See also No. 5586.